OPERATING INSTRUCTIONS

dermalight® 80 psoracomb

UV-B-311nm-narrowband

Art.-no. #200001 (230V 50Hz) Art.-no. #200003 (230V 50Hz)



Before putting the unit into operation and starting the treatment, read these operating instructions carefully.

Dear Sir or Madam,

The **dermalight**[®] **80** is a handy and economical unit used for the treatment of various skin diseases. We hope that you will be satisfied with the **dermalight**[®] **80** too. In order to help you to achieve goods results, please follow these instructions exactly.

Kind regards,

Dr. Hönle Medizintechnik GmbH

CONTENT

1.	Safety Information	2
2.	Description	4
2.1.	General	4
2.2.	Scope of Delivery	4
3.	Operation	5
3.1.	Operation with the Comb Attachment	5
3.2.	Operating Conditions	5
3.3.	Electromagnetic Compatibility	6
4.	Fields of Application and Therapy Information	7
4.1.	Fields of Application	7
4.2.	Therapy Information	7
4.3.	Therapy recommendation	9
5.	Maintenance Information	11
5.1.	Cleaning the Hand Lamp	11
5.2.	Cleaning and Disinfecting the Comb Attachment	11
5.3.	Spare Parts and Accessories	12
6.	Repair and Spare Parts Service	12
7.	Technical Data	13
7.1.	Symbols	14
7.2.	Therapy spectrum	14
8.	Warranty and Liability	15
9.	Environmental Protection	15

Attachment: Patient diary

1. SAFETY INFORMATION

Read the operating instructions carefully before using the dermalight[®] 80 for the first time.



All important safety information is marked with this symbol. Please follow these instructions carefully to prevent health risks and damage to property.



dermalight[®] 80 emits intense UV-radiation which can lead to health damages like sunburn/skin burns, conjunctivitis and keratitis (retina damage), if used improperly, especially when overdosed. Your doctor in charge has to be informed in such cases and has to be seen regularly.

Never operate without UV safety goggles!

Perform therapy only as described in the operating instructions or as recommended by a doctor.

Never use the unit in the bath tub!

Never use the unit when housing or power cable are defect!

The safe handling and smooth operation of the **dermalight® 80** presupposes familiarity with all the basic safety regulations.

The operating instructions contain all essential information on how to operate the equipment safely.

The operating instructions, especially the safety information and safety regulations, must be observed by everyone working with this equipment.

The accident-prevention rules and regulations prevailing at the place of use must also be observed.

Additional safety instructions for doctors/clinics:

The operator (doctor/clinic) has to check the careful operation of the personnel handling the equipment in regular intervals.

Before commencing work, those people who are to work with the dermalight® 80 have to:

- Observe the regulations governing safety and accident prevention.
- Read the chapter on safety and the warnings contained in these operating instructions and to observe these at all times during operation.

Hazards when using the equipment

The **dermalight**® **80** was built according to the state of the art and in compliance with recognized safety standards. The equipment must be used

- only for that purpose for which it was intended,
- only when in perfect working order.

Improper use can endanger the health of the user and/or third parties (including damage to the skin and eyes) as well as impairing the equipment or other items of property.

Any faults which might impair the safety of the equipment must be remedied immediately.

Proper use

The **dermalight**® **80** is a UV-irradiation unit for the treatment of skin diseases.

Any other use of the equipment going beyond this shall be deemed improper and may be hazardous.

The operator may operate the equipment only if all the user information contained in these operating instructions is observed at all times. Failure to do so may render the warranty null and void and jeopardize the success of the therapy.

The operator undertakes to observe the prescribed schedule for inspection and maintenance work and the replacement of wear parts (e.g. lamps) this work entails.

The company Dr. K. Hönle Medizintechnik GmbH shall not be liable for any damage caused by the improper use of the equipment.

Proper use also entails:

- adherence to all the information contained in the operating instructions
- adherence to the schedule for inspection and maintenance work
- adherence to the general and specific safety information and safety regulations contained in these operating instructions as well as the prevailing accidentprevention regulations.

2. **DESCRIPTION**

2.1. GENERAL

dermalight[®] **80** is a medical UV-irradiation unit designed for mobile use. The emission spectrum of its lamps is in the UVB narrowband-range. The lamps contain a small innoxious part of visible light.

Simple and universal use of the **dermalight**® **80** is made possible by its low weight and handy shape. Treatment of the scalp – normally a difficult exercise – is easy to perform with the slip-on comb attachment.



Never start the dermalight® 80 without first putting on safety goggles. UVB-irradiation may harm your eyes!

2.2. SCOPE OF DELIVERY

The **dermalight**[®] **80** is delivered with the following parts:



- dermalight® 80 unit with mains plug
- comb attachment
- Operation instructions with patient's diary



UV-protective googles



LCD-timer



plastic suitcase (optional)

3. OPERATION

Plug the **dermalight**[®] **80** into a mains outlet (230 V / 50 Hz). Operate the **dermalight**[®] **80** only from properly installed socket outlets. The plug should only be operated in horizontal position in order to avoid, that it falls out of the mains outlet (you can use a triple socket assembly). With the rocker switch on the top of the unit you can switch the **dermalight**[®] **80** on and off. After the unit is switched on there may be an ignition delay of up to 30 seconds before the lamps emit a uniform light.

The **dermalight**® **80** is ready for use immediately after lamp ignition, i.e. there is no warm-up period.

3.1. OPERATION WITH THE COMB ATTACHMENT







To use the **dermalight**[®] **80** with the comb attachment (Art.-no. 995200), slip on the attachment from the front of the unit until the two lugs on the comb snap into the recesses in the **dermalight**[®] **80**. The attachment is correctly fitted when the four guide ribs of the comb are inside the guide slots of the **dermalight**[®] **80**. The "dr. hönle"-logo then lies at the front of the **dermalight**[®] **80**.

3.2. OPERATING CONDITIONS

dermalight[®] **80** is designed for use in dry rooms with an ambient temperature never exceeding 45 °C.

Be sure to protect the unit from chemical vapours and never use it in potentially explosive atmospheres.

The unit can be used at any angle.

3.3. ELECTROMAGNETIC COMPATIBILITY

dermalight[®] **80** uses high frequency energy exclusively for its internal function. Therefore its HF-emission is very low and it is unlikely that surrounding electronic devices are disturbed. (HF-emissions acc. to CISPR 11, group 1)

dermalight® **80** is determined for the use in an environment as described below. The user should take care that the unit is used in such an environment.

dermalight® **80** is determined for the use in all facilities, including residential areas and such facilities connected directly to an official supply network, which also supplies buildings and residential buildings. (HF-emissions acc. to CISPR 11, class B)

Magnetic fields at the supply frequency should correspond to the typical values for business and hospital environments.

Portable and mobile radios should not be used at a lower distance to the **dermalight**® **80** including cables than the recommended security distance acc. To the table below:

Nominal capacity of	Security distance depending on the transmitter frequency m		
the transmitter	150 kHz - 80 MHz	80 MHz - 800 MHz	800 MHz - 2,5 GHz
0,01	0,03 m	0,03 m	0,07 m
0,1	0,11 m	0,11 m	0,22 m
1	0,35 m	0,35 m	0,70 m
10	1,11 m	1,11 m	2,21 m
100	3,50 m	3,50 m	7,00 m

4. FIELDS OF APPLICATION AND THERAPY INFORMATION

4.1. FIELDS OF APPLICATION

With the **dermalight**® **80** it is possible to carry out UVB-therapy, depending on the indications.

Indications: Given the latest findings in photodermatology, this means that the following indications can be treated with promise of success:

- Psoriasis
- Alopecia areata
- Vitiligo
- dermalight[®] 80 can be used for local irradiation of small circumscribed areas of skin all over the body, for wrinkles and for the scalp

Contra-indications: Because there are no experiences in the case of pregnancy, you should carry out a UV-therapy only after consulting your doctor in charge. The following contra-indications are valid for all irradiation units:

- Hyperthyroidism
- Lupus erythematosus
- Tumorous skin changes
- Diseased hyperphotosensitivity (e.g. Xeroderma pigmentosa)
- Porphyrin disease
- Floride tuberculosis or other floride processes
- Accompanying medical treatment with potential skin damage or intensified photosensitivity

4.2. THERAPY INFORMATION

The given therapy examples are to be seen as standard values and have to be ^co-ordinated with your doctor.

In order to achieve a steady irradiation intensity at short irradiation times, the unit should be switched on approx. 30 seconds before starting the therapy treatment.

For the therapy success it is essential to pre-treat your skin or scalp, i.e. to remove scale.

For the sake of simplicity we have based the following descriptions on skin type 2 (applies to the majority of Central Europeans).

Guide values for skin type 2, first exposure:

approx. 60 seconds for each irradiated area of the body;

approx. 5-6 minutes for the entire hair-covered scalp.

The duration of the first exposure for hair-covered scalp depends on the extent of the hair covering and its thickness. The purpose of the comb is to part the hair and allow the UV-irradiation to get through to the scalp (see Chapter 4.3. THERAPY RECOMMENDATION).

The guide value for the percentage increase per exposure for skin type 2 is 25% to 30%.



In case of overdose (noticeable and visible sun burn or pronounced reddening of the skin), shorten the irradiation period or discontinue treatment.

Guide values for the maximum **final** exposure time (to complete the irradiation treatment) are:

approx. 3-4 minutes for each irradiated area or

approx. 2 times 20 minutes for the entire hair-covered scalp (f. ex. once in the morning and once in the evening).



UV safety goggles guaranteeing 100% UV protection must be worn during treatment. Suitable goggles are available from Dr. Hönle Medizintechnik (see Chapter 6. SPARE PARTS AND ACCESSORIES).

Use sun lotion with a high sun block factor (≥15) on your forehead and on your ears.

Irradiation intensity decreases as the lamps grow older. This means that you must add an additional 10 - 20 % allowance to the exposure time after approx. 200 - 300 hours in operation. Remember to deduct this allowance again after replacing the old lamps with new ones.

For greater uniformity of irradiation we recommend combing your hair during exposure from left to right and then from the front to the back. Wear a glove on the hand holding the unit to protect it from the UV radiation.

Skin type	Description
	light skin, red- or fair-haired, blue or green eyes, freckles
1	always quick sunburn; scarcely or no bronzing even after repeated treatments (Celtic type)
2	fair-haired, blue, grey or green eyes almost always sunburn; moderate bronzing after repeated treatments (fair European type)
3	light brown or brown hair, brown eyes moderately often sunburn; progressive bronzing after repeated treatments (dark-skinned European type)
4	dark brown or black hair, brown eyes rarely sunburn; quickly beginning and clear bronzing (Mediterranean type)

Table 1: Characteristics of the skin types

4.3. THERAPY RECOMMENDATION

The doctor has to determine the initially treatment time and the increase or decrease of treatment time.

Example 1: Psoriasis of the hair-covered scalp

Therapy:	UV-B-311 nm therapy
Unit:	dermalight® 80 with comb attachment
Patient's skin type:	2 (European average)
Irradiation distance:	2- 3 cm (is kept automatically by the comb attachment)
Duration of first exposure:	approx. 5-6 minutes for the entire scalp
Increase of exposure time per follow-up exposure:	approx. 20 - 30% of previous exposure time
Maximum exposure time:	2 times 20 minutes (entire scalp; e.g. one time in the morning and one time in the evening) per treatment
Duration of treatment:	4 - 6 weeks, longer for particularly serious cases
Frequency of irradiation:	4 - 7 times per week

If skin irritations appear, decrease the treatment time of the following treatment by about 2 minutes. Only increase the time after two further treatments.

Example 2: Psoriasis of a small circumscribed area of skin

Therapy:	UV-B-311 nm therapy
Unit:	dermalight® 80 (with comb attachment)
Patient's skin type:	2 (European average)
Irradiation distance:	approx. 2 - 3 cm
Duration of first exposure:	approx. 45 - 60 seconds per irradiated area
Increase of exposure time per follow-up exposure:	approx. 20 - 30 % of previous exposure time
Maximum exposure time:	approx. 3 - 4 minutes per irradiated area
Duration of treatment:	3 - 4 weeks, longer for particularly serious cases
Frequency of irradiation:	4 - 5 times a week

If skin irritations appear, decrease the treatment time of the following treatment by about 20 seconds. Only increase the time after two further treatments.

Example 3: Treatment of Vitiligo

Distance: 3 cm, use the comb attachment as a distance holder. The comb attachment does

not influence the treatment.

Frequency: 3 times a week

Session	Dose mJ / cm ²	Treatment time minutes : seconds
1.	70	20 sec
2.	140	40 sec
3.	210	1 min
4.	280	1 min 20 sec
5.	350	1 min 40 sec
6.	420	2 min
7.	490	2 min 20 sec
8.	560	2 min 40 sec
9.	630	3 min
10.	700	3 min 20 sec
11.	770	3 min 40 sec
12.	840	4 min
13.	910	4 min 20 sec
14.	980	4 min 40 sec
and all further sessions		

Maximum treatment time: 4 min 40 sec

If skin irritations appear, decrease the treatment time of the following treatment by about 20 seconds. Only increase the time after two further treatments.

5. MAINTENANCE INFORMATION

Daily: Check the filter glass for damage and dirt; check the housing for damage.

Every 400 operation hours / each 2-3 years in private operation:

Replace the lamps.

Every 2 years: Maintenance by our Customer Service or a technician authorized by us

(applies only to commercial users but is recommended to comply with the

Medical Devices Act).

5.1. CLEANING THE HAND LAMP



Disconnect the unit by unplugging the power-pack!

Never wipe the hand lamp or the filter glass with a dry cloth. To clean dusty or dirty surfaces, wipe with a damp soft cloth or sponge (add a little dishwashing liquid to warm water). Anti-static plastic cleaners are also suitable.

Never clean with concentrated disinfectant or solvent such as Sagrotan, Lysoform, methyl alcohol or any other liquid containing alcohol.

5.2. CLEANING AND DISINFECTING THE COMB ATTACHMENT

The comb attachment (Art.-No. 995200) is skin-friendly and hygienic. Its poreless surface makes it difficult for dirt and bacteria to accumulate.

To clean and disinfect the comb, see Section 5.2.

At 25 °C the comb is resistant to the following chemicals:

- Baktolan, up to 5 % - Merfen

- Chinosol, up to 1 % - Perhydrol

- Elmocid Gamma, up to 2 % - Perodin

- Lugol's solution - Sagrotan, up to 2 %

- Mefarol, up to 1 % - Hydrogen peroxide, up to 40 %

- Merckojod, up to 1 % - Zephirol, up to 5%

• Under no circumstances are you to use:

AlcoholBaktolan, concentratedSagrotan, over 2%

- Gasoline mix - Sidolin

- Tincture of iodine, 5% - Spirit of wine

Phenic acidLysoformCarbon tetrachlorideTrichloroethylene

5.3. SPARE PARTS AND ACCESSORIES

•	Lamp UV-B-311 nm (PL-S 9W/01)	ArtNo.	995500
•	Housing with filter	ArtNo.	995210
•	Comb attachment	ArtNo.	995200
•	UV safety goggles with elastic headband	ArtNo.	995000
•	UV safety goggles "professional"	ArtNo.	995001
•	Countdown timer	ArtNo.	995020

Our current price list is available on request.

6. Repair and Spare Parts Service

Please contact our company for warranty claims, repairs and spare parts:

Dr. K. Hönle Medizintechnik GmbH

Tel.: +49 - 8191-30555-0

Viktor-Frankl-Straße 20

Fax: +49 - 8191-30555-50

86916 Kaufering

e-mail: medizin@drhoenle.de

Germany http://www.drhoenle.de

For safety reasons the replacement of parts or the repair of the unit may only be carried out by Dr. K. Hönle Medizintechnik GmbH or by an authorized dealer.

7. TECHNICAL DATA

Type dermalight® 80 psoracomb UV-B-311 nm

Order No. / Power supply 200001: 230V/50Hz

200003: 230V/50Hz

Power consumption 11 W

Lamp 1 x UV-B-311 nm (PL-S 9W/01)

Dimensions (L x W x H) 300 x 60 x 45 mm

Weight (with power cable) 800 g

Irradiation outlet 110 x 40 mm

Operating temperature 5 - 45 °C

MPG class

Protection class II, totally insulated

Marking C € 0123

Manufacturer A.L.T. Lichttherapietechnik

GmbH

Thura Mark 10 D-06780 Zörbig

Tel.: 0049-34956-20056 Fax: 0049-34956-20053

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All technical specifications are subject to technical alterations.

7.1. SYMBOLS



Attention, see operating instructions



Wear UV-protective googles



Part of application type BF



Protection class II

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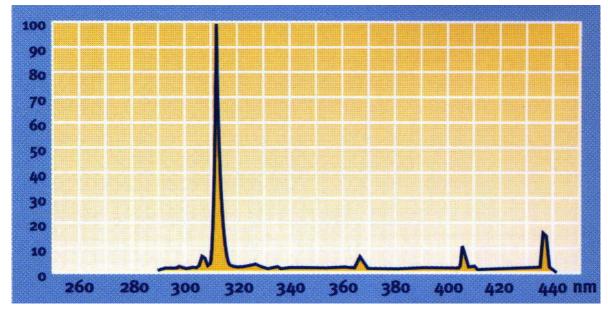
Alternating current



Unit contains electronic parts and may not be disposed in the household rubbish. (see also chapter 9)

7.2. THERAPY SPECTRUM

Relative spectral irradiation distribution (%)



Wavelength [nm]

8. WARRANTY AND LIABILITY

In principle, the General Terms of Sales and Delivery of Dr. K. Hönle Medizintechnik GmbH shall apply. These shall be submitted to the operator upon the signing of contract at the very latest. The warranty for the unit is 12 months (not for lamps). There shall be no warranty or liability claims in the event of personal injury or damage to property if these are attributable to one or more of the following causes:

- the use of the **dermalight**® **80** for a purpose other than that for which it was intended
- failure to observe the information on the assembly, commissioning, operation and maintenance of the unit contained in the operating instructions
- improper assembly, commissioning, operation and maintenance of the dermalight[®] 80
- operation of the dermalight® 80 with defective and/or malfunctioned safety and protective equipment
- unauthorized structural modifications of the dermalight[®] 80
- inadequate checking of wear parts
- repairs performed by persons who are not authorized by Dr. Hönle Medizintechnik
- · catastrophes caused by foreign bodies or acts of God

9. ENVIRONMENTAL PROTECTION

The UV-lamps contain substances, which can harm the environment. Please take care, that the lamps are not disposed with the household rubbish, after having reached their maximum service life. Please take them to official collection points, in order to grant an environmentally suitable disposal.

The **dermalight**® **80** has been constructed for a long-time reliable operation. If you don't want to use **dermalight**® **80** any more, please take care, that the electronic parts must not be disposed with the household rubbish. Please return the unit to your dealer.

